BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES OF THE
STATE OF MONTANA

In the matter of the amendment of ARM 37.85.903 and 37.85.905 pertaining to general Medicaid services, physician-administered drugs	)))))	NOTICE OF PUBLIC HEARING ON PROPOSED AMENDMENT

TO: All Concerned Persons

1. On November 6, 2008, at 2:00 p.m., the Department of Public Health and Human Services will hold a public hearing in the Wilderness Room of the Colonial Building, at 2401 Colonial Drive, Helena, Montana, to consider the proposed amendment of the above-stated rules.

2. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, contact Department of Public Health and Human Services no later than 5:00 p.m. on October 27, 2008, to advise us of the nature of the accommodation that you need. Please contact Rhonda Lesofski, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena MT 59604-4210; telephone (406) 444-4094; fax (406) 444-1970; or e-mail dphhslegal@mt.gov.

3. The rules as proposed to be amended provide as follows, new matter underlined, deleted matter interlined:

37.85.903 PHYSICIAN-ADMINISTERED DRUGS, DEFINITIONS

(1) "340B Drug Pricing Program (340B)" means a federal program administered by the Health Resources and Services Administration (HRSA) which allows qualified entities to purchase pharmaceuticals at a substantially reduced cost under PL 102-585, section 602, of the Veterans Health Care Act of 1992.

(2) "Carve out" means the process by which qualified entities may remove Medicaid clients from 340B program activities and, therefore, purchase pharmaceuticals at a non-340B cost.

~~(1) "Centers for Medicare and Medicaid Services (CMS) Top 20" means the list of National Drug Codes (NDCs) as determined under Section 1927(a)(7)(B) of the Social Security Act requiring the Secretary of CMS to publish a list of the 20 multiple source physician administered drugs with the highest dollar volume dispensed under the Medicaid program.~~

~~(2)~~ (3) "Healthcare ~~c~~Common ~~p~~Procedures ~~c~~Coding ~~s~~System (HCPCS)" means the national uniform coding method maintained by the CMS that incorporates the American Medical Association (AMA) Physicians Current Procedural Terminology (CPT) and the three HCPCS unique coding levels, I, II, and III.

(a) For purposes of physician-administered drugs, HCPCS refers to billable codes ~~that may be cross-walked to NDCs~~ with corresponding rebatable National Drug Codes (NDC).

~~(3)~~ (4) "National Drug Codes (NDC)" means an 11 digit numerical code maintained by the Federal Drug Administration (FDA) under the Drug Listing Act of 1972, that identifies the manufacturer, ~~drug,~~ product, and package size ~~assigned by the Federal Drug Administration (FDA)~~.

~~(4) "Physician administered drugs" means covered outpatient drugs under section 1927(k)(2) of the Social Security Act that are typically furnished incident to a physician's service.~~

~~(a) These drugs are injectable or intravenous drugs administered by a medical professional in a physician's office or other outpatient clinical setting.~~

~~(b) Reimbursement for physician administered drugs is allowed only if the drug is a covered drug under 42 USC 1396r-8.~~

(5) "Physician-administered drugs" means drugs other than vaccines covered under section 1927(k)(2) of the Social Security Act that are typically furnished incident to a physician's services.

(a) Physician-administered drugs are administered by a medical professional in a physician's office or other outpatient clinical setting.

(b) Physician-administered drugs are incident to a physician's services that are separately billed to Medicaid.

(c) Reimbursement for physician-administered drugs is allowed only if the drug qualifies for rebate in accordance with 42 USC 1396r-8.

AUTH: 53-2-201, 53-6-113, MCA
IMP: 53-6-101, MCA

37.85.905 PHYSICIAN-ADMINISTERED DRUGS, BILLING REQUIREMENTS (1) ~~Effective April 1, 2008, all billable claim lines submitted for physician administered drugs must include the NDC, the corresponding HCPCS code, and the units administered for each code.~~ Billable claim lines submitted for reimbursement of physician-administered drugs must:

(a) ~~Claim lines billed for HCPCS that represent physician administered injections will be denied if there is no NDC on the line.~~ include a valid 11 digit NDC;

(b) include the drug quantity billed for each code;

(c) state the NDC unit of measure as one of the following:

(i) international unit - F2;

(ii) gram - GR;

(iii) milliliter - ML; or

(iv) units - UN;

(d) include corresponding CPT/HCPCS codes; and

(e) include a drug price.

~~(b)~~ (2) Reimbursement will be made only on those drugs manufactured by companies that have a signed rebate agreement with the CMS.

~~(2) The requirements of this rule do not apply to claims reimbursed under all-inclusive payment methodologies.~~

(3) A nonrebatable drug with a medically accepted indication may be prior authorized at the department's discretion. Prior authorized drugs will be reimbursed according to provider type.

(4) Drugs and devices purchased under the 340B Drug Pricing Program are exempt from this rule.

(5) Providers participating in the 340B Drug Pricing Program:

(a) shall not submit a NDC for claim lines that are billed utilizing physician-administered drugs purchased under the 340B Drug Pricing Program;

(b) shall submit CPT/HCPCS code(s) with all claims submitted to Montana Medicaid;

(c) shall bill Montana Medicaid their actual acquisition cost; and

(d) must notify Montana Medicaid of newly acquired 340B status immediately upon approval from the Office of Pharmacy Affairs.

(6) Providers may elect to "carve out" Medicaid clients from their 340B program activities when billing non-340B priced physician-administered drugs and register their intent with the Office of Pharmacy Affairs.

(7) Providers who have registered with the Office of Pharmacy Affairs:

(a) shall bill all claims as described in (1)(a) through (f); and

(b) will be reimbursed according to their provider type.

AUTH: 53-2-201, 53-6-113, MCA
IMP: 53-6-101, MCA

4. The Department of Public Health and Human Services (the department) is proposing amendments to ARM 37.85.903 and 37.85.905, pertaining to physician-administered drugs. The proposed rule amendments are necessary to comply with section 1903(i)(10) of the Social Security Act (the Act) prohibiting Medicaid federal financial participation (FFP) for physician-administered drugs unless states submit the utilization data described in section 1927(a) of the Act and limit Medicaid reimbursement for at least the top 20 multiple source physician-administered drugs. States must then obtain rebates from the manufacturers of such drugs.

Description of proposed rule changes

The department is proposing amendments to ARM 37.85.903 and 37.85.905 to help it comply with the utilization data reporting requirements and the rebate requirements for physician-administered drugs.

States are required to obtain rebates on a minimum of 20 multiple source physician-administered drugs with the highest dollar volume dispensed under the Medicaid program and manufactured by companies that have a signed rebate agreement with CMS. States may require the reporting of National Drug Codes (NDC) on all Medicaid physician-administered drug claims for rebate purposes. The department elected to enforce collection of rebates on all reimbursable National Drug Codes to maximize rebate dollars generated which, in turn, will offset the high automation costs associated with NDC collection. The specific proposals are described below.

ARM 37.85.903

The department is proposing amendments to the definitions rule to make the rules easier to read and understand. A new definition specifically describing the "340B Drug Pricing Program" would make these rules easier to understand. The department is also proposing a simplified definition of "physician-administered drugs".

ARM 37.85.905

The department is proposing amendments to this rule to make it easier to read and understand. Physician-administered drugs purchased by providers participating in the 340B Drug Pricing Program under the Public Health Service Act 42 USCA section 256b (Supp. 1998) are exempt from reporting National Drug Codes. The department is proposing an amendment to require such providers to notify it of newly acquired 340B status immediately upon approval from the Office of Pharmacy Affairs. This will make it easier to administer the physician-administered drug program.

Payment to the provider for physician-administered drugs is currently made using the reimbursement methodology for each provider type. The department is proposing an amendment to the rule specifically stating this policy. The reimbursement methodologies would not change as a result of the proposed amendment.

Alternative considered

The department considered and rejected the alternative to the proposed amendments, which would have been to make no changes to the existing definitions or reimbursement provisions. The department's experience with the administration of the physician-administered drug rules indicates that the proposed amendments would make the rules easier to read and understand.

Fiscal Effects

The department expects the proposed amendments to minimally change reimbursement to affected providers. There is no impact to clients. No direct fiscal effects are expected.

Persons and entities affected

The proposed amendments would affect about 5,000 physicians, mid-level practitioners, and other professionals as well as about 350 hospitals, birthing centers, and other outpatient medical service providers.

5. Concerned persons may submit their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be

submitted to: Rhonda Lesofski, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena MT 59604-4210, telephone (406) 444-4094; fax (406) 444-1970; or e-mail dphhslegal@mt.gov, and must be received no later than 5:00 p.m., November 13, 2008.

6. The Office of Legal Affairs, Department of Public Health and Human Services, has been designated to preside over and conduct this hearing.

7. The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies for which program the person wishes to receive notices. Notices will be sent by e-mail unless a mailing preference is noted in the request. Such written request may be mailed or delivered to the contact person in 5 above or may be made by completing a request form at any rules hearing held by the department.

8. An electronic copy of this Proposal Notice is available through the Secretary of State's web site at http://sos.mt.gov/ARM/Register. The Secretary of State strives to make the electronic copy of the Notice conform to the official version of the Notice, as printed in the Montana Administrative Register, but advises all concerned persons that in the event of a discrepancy between the official printed text of the Notice and the electronic version of the Notice, only the official printed text will be considered. In addition, although the Secretary of State works to keep its web site accessible at all times, concerned persons should be aware that the web site may be unavailable during some periods, due to system maintenance or technical problems.

9. The bill sponsor notice requirements of 2-4-302, MCA, do not apply.

/s/ John Koch
Rule Reviewer

/s/ Joan Miles
Joan Miles, Director
Public Health and Human Services

Certified to the Secretary of State September 29, 2008.